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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,227	09/23/2002	Allan J Clarke	P32374	9571

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,227	CLARKE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 38-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 38-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Information Disclosure Statement filed 01/30/02, and Response to Notice File Missing Parts filed 09/23/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 68 does not provide how one of ordinary skill in the art put the capsule compartments together to obtain a multi-component pharmaceutical dosage form. It appears from claim 68 that the finish products obtained are two separate capsule compartments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 38, 39, 51-56, 58, 59 and 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodhart et al. US 5,074,426.

Goodhart discloses a multi-units capsule dosage comprising first and second capsule units (column 3, lines 17-19). Column 4, lines 1-31 disclose the process of preparing the capsule units comprising filling the two capsule units with medicinal preparation, applying adhesive paste on top of the medicinal preparation, turning the capsule units inwardly towards each other with the adhesive paste abutting each other, and adhesive paste would be applied to secure the capsule units together (Fig. 7). The multi-capsule units can be connected by separately molded section which is sealed to the capsule units by solvent welding (column 4, lines 28-31, Fig 3). Goodhart also teach there is an intermediated molded locking part used to secure the two capsule units together (column 4, lines 44-66). Furthermore, the capsule units are made with a female member (68) and male member (70) to provide a tight friction fit (Figs. 13&14, column 5, lines 5-16). Goodhart also teach the capsule units are detachable joined by adhesive, banding, or locking mechanical means (see abstract).

It is noted that Goodhart does not expressly teach the capsule units are soluble or disintegrable in a patient's gastrointestinal environment. However, it is the position of the examiner that the limitation is inherent because Goodhart teaches the capsule units are made of gelatin or suitable material (column 3, lines 57-59). It is well known in the pharmaceutical art that gelatin capsule disintegrates in the intestinal environment (see Wagner at column 1, lines 35-36 for reference).

Claims 1, 38, 42-44, 58, and 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Graham US 5,085,033.

Graham discloses a capsule formulation comprising active agent in matrix material (see abstract, column 3, lines 9-25). The active agent and matrix materials are filled in capsule halves, the capsule halves are sealed by the application of electromagnetic radiation whereupon the capsule halves are welded to each other (column 4, lines 19-29). Column 8 and examples 1-14 disclose the process for filling the capsule.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 38-41, 51-59 and 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodhart et al., in view of Sivaramakrishnan et al. WO 90/11070 (Sivara).

Goodhart is relied upon for the reason stated above. Goodhart teaches the capsule can be filled with pellets, granules or viscous or liquid substance (column 3, lines 63-65), however, the reference is silent as to the teaching of capsule containing solid matrix as claimed in claims 40 and 41.

Sivara teaches a controlled release delivery device comprising a water-soluble capsule surrounding an inner capsule containing solid matrix core (see abstract, page 5, lines 8-19, and page 10, lines 13-34). The solid matrix core can be in the form of microcapsule (page 7, lines 1-17 and page 9, lines 14-34). Sivara also teach different wall thickness of the matrix shell that would promote different rates of release of active agent (page 11, lines 25-34). Thus, it would have been obvious for one of ordinary skill in the art to modify the capsule composition of Goodhart to encapsulate the solid matrix in view of the teachings of Sivara with the expectation of providing a capsule formulation containing multi-unit capsule compartments suitable for multi-release rates of active agents.

Claims 1 and 38-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodhart et al., in view of Amidon et al. US 5,674,530.

Goodhart is relied upon for the reasons stated above. The reference is silent as to the teaching of the linker as claimed in claims 44-50.

Amidon discloses a delivery system comprising multiple chambers and multiple plugs (linker) (column 3, lines 59 through column 4, lines 1-36). Thus, it would have been obvious for one of ordinary skill in the art to modify the capsule formulation of Goodhart using the plug in place of the adhesive paste in view of the teaching of Amidon with the expectation of providing a true pulsatile delivery system that increases in bioavailability and provides optimal dosing schedule for two or more drugs.

It is noted that the cited references do not teach the wall thickness of sub-unit (multi-compartment). However, changes in size or shape is not patentably distinct the claimed invention because it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable wall thickness depending upon the desirability of the permeability rate of the drug.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Echenhoff et al. and Barnwell et al. are cited as being of interest for the teachings of multi-compartment capsule.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600